



STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES
503b Outsourcing Inspection



File #
Insp #

NAME	PERMIT NUMBER	DATE OF INSPECTION	
DOING BUSINESS AS			
STREET ADDRESS		TELEPHONE #	EXT
CITY	COUNTY	STATE/ZIP	

License Relations

Pharmacy Affiliate

	License #
	License #

Special Sterile Compounding

	License #
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Quality - 21CFR part 211 subpart B

Firm has an independent Quality Control Unit.	
The QC unit has the authority and responsibility to approve or reject all components, drug product containers or closures, end process materials, packaging materials, labeling and drug products.	
QC unit reviews and approves/rejects: SOP's, Batch Records (completeness and accuracy, components, API's, materials, OOS results.	
Investigations are conducted within time limits specified per SOP.	
All written quality procedures are current and approved.	
The QC unit follows their procedures.	
QC unit personnel are qualified through training and experience.	
The production batch record and release test results are reviewed for accuracy and completeness prior release of finished product.	

Facilities and Equipment - 21CFR part 211 subpart C and subpart D

The facility design is suitable for compounding sterile products.	
The layout and organization of the facility is designed to prevent contamination and mix ups.	
The control of air pressure, dust, humidity and temperature is adequate for the manufacturing, processing, storage or testing of drug products.	
Pressure gauges that monitor pressure differentials are calibrated.	
The facility is maintained in a clean and sanitary condition.	
Certifications conducted under dynamic, worst case conditions with the maximum number of personnel allowed per SOP present.	
The facility has written procedures that describe in sufficient detail the cleaning schedule, methods, equipment and material.	
The facility has a procedure for rotating cleaning solutions.	
Sporicidal agents are used. How often?	
The facility has documentation of the effectiveness of the cleaning solutions.	
Primary and secondary engineering controls currently certified.	
Ceiling tiles are clean room grade and gasketed and sealed/clipped.	
Air return vents are not blocked.	
HEPA filters are all leak tested.	
Compounding of hazardous drugs is clearly separated from non-hazardous drugs to prevent cross contamination.	
All equipment has written procedures for use.	
Facility has documentation of equipment calibration, maintenance, cleaning.	
All equipment is validated for its intended use.	
Refrigerators and freezers are monitored with a calibrated thermometer.	

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Documentation of training personnel on use of equipment.	
Surfaces that contact materials or finished goods non-reactive, non-adsorptive and non-additive.	

Personnel Qualification - 21CFR part 211.25; 211.28

All personnel involved in the preparation and handling of csp's are trained and qualified in their roles.	
Facility has a written training program that describes the required training, frequency of training and process for evaluating the performance of individuals involved in sterile compounding.	
Facility has documentation that compounding personnel have the required skills necessary to perform their assigned task.	
Compounding personnel receive ongoing periodic GMP training by GMP trainers.	
Are GMP trainers qualified through experience and training.	
Prior to beginning to prepare CSP's personnel have completed training and have demonstrated proficiency in the principles and hands on skills of aseptic manipulations.	
Compounding personnel have ongoing training for specific tasks they are authorized to perform.	
Personnel have been periodically trained in core competencies, visual observation is conducted to confirm personnel have necessary skills (i.e. Hand hygiene and garbing, aseptic manipulations, cleaning and disinfecting).	
Personnel sampling including GFT is conducted after compounding and documented on each batch record.	
Personnel have completed media fill simulations for all aseptic compounding under the most difficult and challenging processing conditions which include the most manipulations/units, most complex flow of material, longest time to compound and all breaks.	
Personnel are retrained and requalified after failure of media fill, GFT or batch failures.	

Environmental Monitoring - 21CFR 211.113

Facility has an environmental monitoring program.	
Air quality is monitored regularly using volumetric air sampling to ensure the environment remains suitable for sterile compounding.	
Settling plates are used during compounding to monitor the quality of air during compounding processes and documented in the batch records.	
Surface sampling is conducted after each batch prior to cleaning and documented on batch records.	
Surface sampling is routinely conducted in all classified spaces in those locations identified to be at highest risk of contamination.	
Media used in environmental and personnel monitoring has been shown to promote the growth of microorganisms and contains agents to neutralize cleaning solutions and disinfectants.	
Sampling data is collected and reviewed on a periodic basis as a means of evaluating the overall state of control of the compounding environment.	
Adverse changes in the environment are investigated and promptly remediated.	
Alert and action levels for CFU counts have been established in SOP's for the facility.	
Air pressure differentials are continuously monitored and demonstrate that a cascading pressure differential is maintained throughout the compounding area during production of sterile compounding.	

Materials - 21CFR part 211.72; 211.80; 211.82; 211.84; 211.94

Facility has a quality agreement with API suppliers to ensure all API's are manufactured in registered FDA facilities.	
Facility tests API's for identity, strength and purity to confirm the specifications in the Certificate of Analysis.	
Facility maintains and follows SOP's for testing of incoming materials.	
Facility has appropriate sterile PPE.	
Materials for cleaning the PEC's are sterile and the effectiveness is validated.	
Filters used for sterilization have documentation that they are compatible with the product, are pharmaceutical grade, non-pyrogenic and capable of sterilizing the intended volume.	
Integrity testing is conducted on all filters used to sterilize product.	
All materials are quarantined until approved by the QC department.	
Written procedures identify storage times beyond which materials must be reexamined before use.	
Release of re tested material clearly identified for reuse.	
Written procedures identify steps in the materials for production.	
Written procedures include release by QC, documentation of correct weight or measure and proper identification of containers.	

Production - 21CFR part 211 subpart F

Materials are sanitized prior to introduction into the clean room.	
All glassware is depyrogenated and cycles are validated and documented.	
Autoclaved cycles are properly validated with BI's.	
Sterilization methods are validated.	
All components are identified on batch records and traceable to the finished product.	
SOP's identify hold times for depyrogenated glassware and the hold times have been validated.	
Deviations and OOS's are adequately documented and thoroughly investigated.	
Facility maintains complete batch records for all compounded sterile products.	

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Facility maintains separate, complete, readily retrievable records of dispensing into the State of Florida.	
Written procedures indicate how and who verifies that correct containers and packages are used for the finished product.	
All finished products are held in quarantine until QC has completed testing and releases the batch.	
Personnel who conduct visual inspection of finished products have been qualified through training and yearly eye exams.	
Firm has an SOP for adverse event reporting to FDA.	
Firm has record of adverse event reports submitted to FDA.	

Labeling - 21 CFR part 211 subpart G

Written procedure specifies who is authorized to issue labels.	
Written procedure specify how labels are issued, used, reconciled with production, returned when unused, and the specific steps for evaluation of any discrepancies.	
Written procedures call for the destruction of excess labeling on which lot and control #'s have been stamped or imprinted.	
Written procedures require that representative samples of units be visually examined upon completion of packaging to verify correct labeling.	
Drug labels include the statement "this is a compounded drug, the name, address and phone # of the facility.	
The label of the drugs contains the lot or batch #, the established name of the drug, dosage form and strength, quantity or volume, the date the drug was compounded, the expiration date, storage and handling instructions, NDC # (if available), the statement "not for resale" and a list of active and inactive ingredients identified by established name and the quantity or proportion of each ingredient and route of administration.	
The label or container contains the following: www.fda.gov/medwatch and 1-800-FDA-1088.	
Written procedures detail how equipment is to be checked immediately prior to use for removal of any labels and labeling from prior print operations.	

Laboratory - 21 CFR part 211 subpart I

Contract labs are FDA registered.	
Facility has qualified their contract labs.	
All products have stability studies to justify the BUD.	
Stability studies, microbial effectiveness testing on the preservative, container closure studies and sterility testing have been conducted to ensure the CSP continues to meet all specifications over the intended shelf life of the product.	
Sterility testing for all batches is conducted using a USP 71 test.	
Method suitability has been conducted for all products.	
Endotoxin testing is conducted on all batches.	
Potency is conducted on all batches.	
Appropriate # of articles/volume is tested for sterility.	
Facility maintains and follows SOP for product release.	
Facility has approved finished product specifications for all csp's.	

Remarks:

I have read and have had this inspection report and the laws and regulations concerned herein explained, and do affirm that the information given herein is true and correct to the best of my knowledge. I have received a copy of the Licensee Bill of Rights.

Investigator/Sr. Pharmacist Signature:

Representative:

Date:

Date: